UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,739	02/21/2002	Walter Callen	09010-107001 / DIVER1530-	1077

45975 7590 08/09/2005

DIVERSA C/O MOFO S.D.
3811 VALLEY CENTER DRIVE, SUITE 500
SAN DIEGO, CA 92130

EXAMINER	
RAO, MANJUNATH N	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/081,739	CALLEN ET AL.	
	Examiner	Art Unit	
	Manjunath N. Rao, Ph.D.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *49-73,95-100,107,111-115 and 117-122* is/are withdrawn from consideration.

5)☒ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5,6,11,12,15,16,29,47,48,74,75,87,88,101-106 and 125-132* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 3/05 & 4/05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-2, 5-6, 11-12, 15-16, 29, 47-75, 87-88, 95-107, 111-115, 117-122, 125-132 are currently pending and are present for examination. Claims 1-2, 5-6, 11-12, 15-16, 29, 47-48, 74-75, 87-88, 101-106, 125-132 are now under consideration. Claims 49-73, 95-100, 107, 111-115, 117-122 remain withdrawn from consideration as being drawn to non-elected invention.

Applicants' amendments and arguments filed on 5-25-05, have been fully considered and are deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 102, 105-106 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 102, 105-106 recite the phrase "a host cell comprising..." and specifically in claim 106 "metabolically rich hosts". Such a limitation could very well read on the transformation of a cell attached to a human being even though all the cells in a human being may not be transformed with said DNA. Claims that read on human being are considered non-statutory subject matter and therefore claims 102, 105-106 are rejected. Amending the claim to recite, for example, "an isolated host cell transformed with the nucleic acid of claim 1" would overcome this rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, and claims 5-6, 11-12, 15-16, 29, 47-48, 74-75, 87-88, 101-106, 125-132 depending therefrom rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims in question recite the phrase "to a sequence as set forth in..". the metes and bunds of the above phrase in the context of the claims in question are not clear to the Examiner. It is not clear whether the polynucleotide claimed is directly referring to the full length of SEQ ID NO associated with the phrase or whether the SEQ ID NO referred is just a representative of the sequence claimed or the per cent sequence identity is "to a sequence of SEQ ID NO:_" meaning to a fragment of said SEQ ID NO. Examiner suggests cancellation of the phrase in all the claims where it is recited and refer directly to the "SEQ ID NO" as " having at least ___% sequence identity to SEQ ID NO:__".

Claims 102, 105-106 are rejected under rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 102, 105-106 recite the phrase "a host cell comprising...". It is not clear from the above phrase whether the host cell is actually transformed with said polynucleotide, because the host cell can continue to "comprise" said polynucleotide even if the polynucleotide is sticking just to the outer surface of the cell.

Examiner suggests amending the claim to recite "an isolated host cell transformed with the polynucleotide of claim 1" in order to render the claim more definitive.

Claim 125 is rejected under rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 125 recites the phrase "and (b) sequences complementary to (a)". This entire phrase is not clear because after the phrase "wherein the nucleic acid encodes a polypeptide having α amylase activity" there is no part (a) but the phrase is recited as "and (b)". It is not clear where is "part (a)". Furthermore, it is not clear whether sequences comprising sequences complementary to (a) have any encoding activity. Examiner requests clarification.

Claim 128 is rejected under rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 128 recites the phrase "95% sequence identity to SEQ ID NO:1 over at least 150 consecutive amino acid residues..". Since SEQ ID NO:1 is a polynucleotide, it is not clear to the Examiner as to whether applicants are referring to polynucleotide or the polypeptide.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 74-88 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 74 is drawn to a nucleic acid probe comprising a nucleic acid sequence wherein said probe hybridizes under stringent conditions which comprises a wash step for 30 minutes at room temperature in a solution of 150 mM NaCl, 20mM Tris hydrochloride, pH 7.8, 1 mM Na_2EDTA, 0.5% SDS followed by a second 30 min wash in the same solution. However, a perusal of the specification indicates that applicants have no support for this wash step of the hybridization. While Examiner found support for "hybridization under stringent conditions" on page 18 (paragraph 0071 and 0072) of the specification, he was unable to fund support for the specific wash conditions recited in the claim. Therefore claim 74 is rejected for introducing "new matter" into the claims.

Claims 1-2, 5-6, 11-12, 15-16, 29, 47-48, 74-75, 87-88, 101-106, 125-132 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide with SEQ ID NO:1 encoding an enzyme with SEQ ID NO:2, having amylase activity, does not reasonably provide enablement for any polynucleotide comprising a polynucleotide having 90%, 93%, 95%, 97%, 98% sequence identity with SEQ ID NO:1 or a polynucleotide probe that has 97% sequence identity over 75 nucleotides, or 95% sequence identity over at least 150 nucleotides, or 90% sequence identity over at least 300 nucleotides of SEQ ID NO:1 wherein said probe hybridizes to **any** amylase-encoding polynucleotide at room

temperature under the hybridization conditions claimed in claim 74 or polynucleotide probe that has 97% sequence identity over 75 nucleotides, or 95% sequence identity over at least 150 nucleotides, or 90% sequence identity over at least 300 nucleotides of SEQ ID NO:1 wherein said polynucleotide encodes a polypeptide with α-amylase activity or polynucleotide that has 97% sequence identity over 100 nucleotides, or 95% sequence identity over at least 200 nucleotides, or 90% sequence identity over at least 400 nucleotides of SEQ ID NO:1 wherein such polynucleotides encodes a polypeptide having α-amylase activity or polynucleotide that encodes a polypeptide with α-amylase activity wherein said polypeptide has at least 99% sequence identity over 40 consecutive amino acids, or 97% sequence identity over 75 consecutive amino acids, or 95% sequence identity over 150 consecutive amino acids of SEQ ID NO:2, or polynucleotide that encodes a polypeptide with α-amylase activity wherein said polypeptide has at least 99% sequence identity over 50 consecutive amino acids, or 97% sequence identity over 100 consecutive amino acids, vectors, host cells comprising the above and method of making the polypeptide encoded by said polynucleotide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 1, 5-6, 11-16, 29, 47-48, 74-92, 101-106, 123-124 are so broad as to encompass any polynucleotide comprising a polynucleotide having 90%, 93%, 95%, 97%, 98% sequence identity with SEQ ID NO:1 or polynucleotide probe that has 97% sequence identity over 75 nucleotides, or 95% sequence identity over at least 150 nucleotides, or 90% sequence identity over at least 300 nucleotides of SEQ ID NO:1 wherein said probe hybridizes to **any** amylase-encoding polynucleotide at room temperature under the hybridization conditions claimed in claim 74, or wherein such polynucleotides encodes a polypeptide having α-amylase activity (Claim 125) or polynucleotide that has 97% sequence identity over 100 nucleotides, or 95% sequence identity over at least 200 nucleotides, or 90% sequence identity over at least 400 nucleotides of SEQ ID NO:1 wherein such polynucleotides encodes a polypeptide having α-amylase activity (claim 126) or polynucleotide that encodes a polypeptide with α-amylase activity wherein said polypeptide has at least 99% sequence identity over 40 consecutive amino acids, or 97% sequence identity over 75 consecutive amino acids, or 95% sequence identity over 150 consecutive amino acids of SEQ ID NO:2 (claim 128), or polynucleotide that encodes a polypeptide with α-amylase activity wherein said polypeptide has at least 99% sequence identity over 50 consecutive amino acids, or 97% sequence identity over 100 consecutive amino acids, (claim 129), vectors, host cells comprising the above and method of making the polypeptide encoded by said polynucleotide. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polynucleotides broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge

of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide and encoded amino acid sequence of a single polynucleotide with SEQ D NO:1. It would require undue experimentation of the skilled artisan to make and use the claimed polypeptides. The specification is limited to teaching the use of SEQ ID NO: 1 as that encoding an amylase but provides no guidance with regard to the making of variants and mutants or with regard to other uses. In view of the great breadth of the claim, amount of experimentation required to make the claimed polypeptides, the lack of guidance, working examples, and unpredictability of the art in predicting function from a polypeptide primary structure (e.g., see Ngo et al. in The Protein Folding Problem and Tertiary Structure Prediction, 1994, Merz et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495), the claimed invention would require undue experimentation. As such, the specification fails to teach one of ordinary skill how to use the full scope of the polypeptides encompassed by this claim.

While enzyme isolation techniques, recombinant and mutagenesis techniques are known, and it is routine in the art to screen for multiple substitutions or multiple modifications as encompassed by the instant claims, the specific amino acid positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

On similar lines, claims directed to nucleic acid probes comprising oligonucleotides described above can hybridize to any polynucleotide encoding alpha amylase i.e., a variant or mutant of SEQ ID NO:1 irrespective of whether the polynucleotide comprising the same encodes a polypeptide with SEQ ID NO:2. The specification does not teach as to how those skilled in the art can use the same to detect a polynucleotide with SEQ ID NO:1 or a polynucleotide encoding a polypeptide with SEQ ID NO:2.

The specification does not support the broad scope of the claims which encompass all modifications and fragments of any polynucleotide encoding an amylase with sequence identity as described above because the specification does not establish: (A) regions of the polynucleotide structure or the encoded polypeptide structure which may be modified without affecting their activity; (B) the general tolerance of amylase encoding polynucleotide to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residue of the encoded polypeptide with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including polynucleotides encoding an enormous number of amino acid modifications of the amylase with SEQ ID NO:2. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of amylase encoding polynucleotides having the desired biological characteristics is unpredictable and the experimentation left to those skilled

in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

In response to the previous Office action, applicant has traversed the above rejection arguing that the specification is indeed enabling to make and use all the different variants claimed.

Applicants argue at length that the Office has not make a case for non-enablement. Applicant argues that the reference of Ngo et al. cited by the Examiner is not relevant and that the relevant issue regarding enablement is not whether one can predict function from a polypeptide primary structure but rather it would take undue experimentation to screen/test for enzyme activity after making any particular amino acid residue change. Applicant also argues "how to make the many possible variants is not an issue". Examiner respectfully disagrees with such an argument. It is very much relevant to the enablement of an invention that applicants teach as to how to make and use the claimed invention. Applicant's conclusion that the relevant issue is whether it would take undue experimentation to screen/test for enzyme activity is highly misplaced. The question that is raised is if one skilled in the art is not provided specific guidance as to how to make the claimed invention in the first place the question of testing or screening does not arise at all. Furthermore, the issue of "undue experimentation' applies to both the method of making as well as testing or screening and to argue that it applies to only screening or testing the invention is a highly misplaced argument. Therefore irrespective of what applicant's conclude about the Ngo et al. reference the above claims are not enabled. Furthermore, Examiner has provided the Ngo et al. reference only to show that even if one generates a large number of random variants from SEQ ID NO:1, it would not be possible to predict the function of the encoded polypeptides as

having amylase activity just by determining the primary amino acid sequence. Examiner respectively disagrees with the applicant's conclusion that Ngo et al. actually supports the idea that most changes in a polypeptide's amino acid sequence will result in little or no effect on its specificity or activity, and that one of skill in the art could easily target a minimum number of residues to predictably generate a limited number of nucleic acid variants to generate desired activity. Applicant also provides the Declaration by Jay Short who declares that the using the specification one of ordinary skill in the art would have been able to routinely make and use the claimed genus of the polynucleotides and polypeptides. Dr. Short also declares that it would not have been necessary for the skilled in the art to understand which regions of the amylases could be modified without the loss of the function or activity. Here again Examiner respectfully disagrees with such an argument. This is because, while methods to produce variants of a known sequence such as site-specific mutagenesis, random mutagenesis, etc. are well known to the skilled artisan, producing variants as claimed by applicants requires that one of ordinary skill in the art know or be provided with guidance for the selection of which of the infinite number of variants have the claimed property. Instant claims are directed to a variants of all types (see above). Thus, in order to make the full scope of recited polynucleotides encoding polypeptides, one skilled in the art has to modify the nucleotides of the sequence of SEQ ID NO:1, comprising 1311 nucleotides encoding a polypeptide comprising 436 amino acids. As noted in the Office action, the polypeptide variants encompass those having a single amino acid substitution, addition, deletion, or insertion and any combination of amino acid substitutions, additions, deletions, and/or insertions. Although the claims are not limited to variants having only a single amino acid substitution, in order to generate for example, only

single amino acid variants of each amino acid of SEQ ID NO:2, one must make 19^{436} variants just for *single amino acid variants*. Thus, at a minimum, the number of variants is 19^{485} and the number becomes seemingly infinite when one considers that the claims broadly encompass simultaneous other alterations by substitution, addition, deletion, and/or insertion. Therefore, while methods to produce variants of a known sequence, e.g., site-specific mutagenesis and random mutagenesis, are well-known to the skilled artisan, producing the claimed variants requires that one of skill in the art know or be provided with guidance for the selection of which of the at least 19^{485} variants has the desired activity. Without such guidance one of ordinary skill would be reduced to the necessity of producing and testing all of the at least 19^{485} possible variants. The art clearly *does not* typically engage in the screening of 19^{485} single amino acid variants and it follows that the art does not typically engage in the screening of $>19^{485}$ variants to isolate those relatively few variants that would have the desired activity. This would clearly constitute undue experimentation. While enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, the specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. Such guidance has not been provided in the instant specification. As such, based on a determination by weighing all of the factual considerations of In re Wands, the examiner has made a determination that the specification does not enable the claimed invention without undue experimentation. Hence the above rejection is maintained.

Claim 29 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of DNA molecules.

The specification does not contain any disclosure of the function of all DNA sequences encoding a polypeptide having at least 95% sequence identity with SEQ ID NO:2. The genus of DNAs that comprise these above DNA molecules is a large variable genus with the potentiality of encoding many different proteins. Therefore, many functionally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses only a single species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

In response to the previous Office action, applicants have traversed the above rejection arguing that Office notes it is concerned about the size of the claimed genus of nucleic acids used in the compositions and methods of the invention and that the instant amendment to the claimed invention addresses the Office's concerns about the size of genus. Examiner respectfully disagrees with such a conclusion. As stated in the previous Office action and in the instant Office action above, the genus comprises a large number of species that have not been described i.e., many functionally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. Applicant argues that the claim is now directed to nucleic acids comprising, inter alia, sequences encoding a polypeptide having an amino acid sequence having at least about 95% sequence identity to a sequence as set forth in SEQ ID NO:2. However even such an amendment does not satisfy the written description requirement since

again many functionally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. Hence the rejection is maintained. Examiner suggests reiteration of the function of the encoded polypeptides in the above claims to overcome the rejection.

Claims 125-132 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of DNA molecules comprising a polynucleotide having 97% sequence identity over a region of 75 or 100 nucleotides or 95% identity over at least 150-200 nucleotides, 90% identity over 300-400 nucleotides of SEQ ID NO:1 encoding a polypeptide with amylase activity or polynucleotides encoding a polypeptide having 99% sequence identity over a regions of 40-50 amino acid residues or 97% identity over at least 75-100 amino acids or 95% identity over 150 amino acids of SEQ ID NO:2, vectors and host cells comprising the same and method of making said polypeptides.

These claims are directed to a genus of polynucleotides comprising a short structural similarity with SEQ ID NO:1 or 2. As discussed in the written description guidelines the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. A representative number of species means that the species which are adequately described are representative of the entire genus. Thus,

when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The specification teaches the isolation and characterization of only a single species i.e., SEQ ID NO:1, 2. Moreover, the specification fails to describe any other representative species by sufficient identifying characteristics or properties to show that applicant was in possession of the claimed genus. The identifying characteristics recited in above claims i.e., polynucleotide having 97% sequence identity over a region of 75 or 100 nucleotides or 95% identity over at least 150-200 nucleotides, 90% identity over 300-400 nucleotides of SEQ ID NO:1 encoding a polypeptide with amylase activity or polynucleotides encoding a polypeptide having 99% sequence identity over a regions of 40-50 amino acid residues or 97% identity over at least 75-100 amino acids or 95% identity over 150 amino acids of SEQ ID NO:2, which altogether include a small percent of structural description of about 5% of the structure of the single disclosed species (for example, 75 nucleotides from the nearly 1400 nucleotides of SEQ ID NO:1), does not include sufficient characteristics to limit the claimed genus to polynucleotides which are not highly variable in both structure and function. The claims include species in which up to 95% of the polynucleotide sequence and up to 80% of the encoded amino acid sequence of the single disclosed species has been substituted as well as allowing alterations in functional characteristics such as substrate specificity, temperature optima, pH optima, and inhibitor/activator profiles. Therefore, the species within the genus are highly variable in both structure and function. As even small changes in structure can change any one of the properties of SEQ ID NO:1 or 2, inclusion of all of the members that fall in the instantly claimed genus together leads one to a conclusion that the recited genus is highly variable in structural or functional characteristics. Thus for all the reasons discussed, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Conclusion

None of the claims are allowable.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 571-272-0939. The Examiner can normally be reached on 7.00 a.m. to 3.30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306/9307 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Manjunath N. Rao, Ph.D.
Primary Examiner
Art Unit 1652

August 4, 2005

Continuation of Disposition of Claims: Claims pending in the application are 1,2,5,6,11,12,15,16,29,47-75,87,88,95-107,111-115,117-122 and 125-132.